IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

SANDY SYKES, ADMINISTRATOR OF THE ESTATE OF DAVID JOHN MUIR
7907 Cincinnati-Dayton Road
West Chester, Ohio 45069

And

SANDY SYKES, INDIVIDUALLY
7907 Cincinnati-Dayton Road
West Chester, Ohio 45069

And

KATHERINE MUIR
621 Clemmer, Apt. 4
Cincinnati, Ohio 45219

And

MARGARET MUIR
P.O. Box 5701
Santa Fe, New Mexico 87502

And

ROBERT MUIR
P.O. Box 146
Deadwood, Oregon 97430

And

Case No: 1:10CV688

Judge: J. BERTELSMAN

COMPLAINT WITH JURY DEMAND ENDORSED HEREON

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ERIC MUIR
2005 Tasca Street, # 101
Las Vegas, Nevada 89128

And

PAUL A. MUIR
93246 Bassonette Road
Deadwood, Oregon 97430

Plaintiffs,

Vs.

UNITED STATES OF AMERICA FOR THE VETERANS ADMINISTRATION
UNITED STATES ATTORNEY
SOUTHERN DISTRICT OF OHIO
ATTN: CIVIL PROCESS CLERK
221 East Fourth Street, Suite 400
Cincinnati, Ohio 45202
UNITED STATES DEPARTMENT OF JUSTICE
ATTN: HONORABLE ERIC C. HOLDER, JR. ATTORNEY GENERAL
950 Pennsylvania Avenue Northwest
Washington D.C. 20530-0001

And

JEFFREY GOLDSMITH, M.D.
UNIVERSITY OF CINCINNATI
DEPARTMENT OF PSYCOLOGY
CINCINNATI VMAC, DIRECTOR OF ALCOHOLISM CLINIC
CINCINNATI, OHIO (N.K.A. CROSSROADS CENTER)
CINCINNATI, OHIO

And

GARY ROSELL, M.D.
VETERANS ADMINISTRATION
3200 Vine Street
Cincinnati, Ohio 45220

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:

And

:

ROBERT WEESNER
VETERANS ADMINISTRATION :
3200 Vine Street
Cincinnati, Ohio 45220 :

And :

CHARLES MENDENHALL. M.D. :
V.A. MEDICAL CENTER
3200 Vine Street :
Cincinnati, Ohio 45220

:

And

:

JUDITH HARRER
V.A. MEDICAL CENTER :
3200 Vine Street
Cincinnati, Ohio 45220 :

And :

THE UNIVERSITY OF CINCINNATI :
MEDICAL CENTER (N.K.A. UNIVERSITY
HOSPITAL) :
G-44 Health Professions Building
P.O. Box 6770573 :
Cincinnati, Ohio 45267-0573

:

And

:

ROCHE MOLECULAR SYSTEMS, INC.
4300 Hacienda Drive :
Pleasanton, California 94588-2722

:

And

:

JOSEPH MORELLI, M.D.
V.A. MEDICAL CENTER :
3200 Vine Street
Cincinnati, Ohio 45220 :

And :

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CENTOROC ORTHO BIOTECH PRODUCTS, L.P.
C/O CENTOROC
800 Ridgeview Drive
Horsham, Pennsylvania 19044

And

SCHERING CORPORATION
SCHERING PLOUGH CORPORATION
2000 Galloping Hill Road
Kenilworth, New York 07003

And

ROCHE PHARMACEUTICALS
(A.K.A. HOFFMANN-LA ROCHE INC.)
340 Kingsland Street
Nutley, New Jersey 07110-1199

And

AMGEN MANUFACTURING LIMITED
A SUBSIDIARY OF AMGEN, INC.
One Amgen Center Drive
Thousand Oaks, California 91320-1799

And

UNITED STATES DEPARTMENT OF VETERAN AFFAIRS
810 Vermont Avenue, NW
Washington, D.C. 20420

And

GLARO SMITH KLINE RESEARCH
Triangle Park, North Carolina 27709

Defendants.

RECITALS

1. Patient means David John Muir;

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2. The time in question means 05/15/2000 to 02/06/2004;
3. The Hamilton County Coroner's Office Death Records is attached as Exhibit A;
4. Patient's claim for damage, injury, or death is attached as Exhibit B with verification of service attached as Exhibit C;
5. Patient's Amended Claim dated 06/18/2010 is attached as Exhibit D with service attached as Exhibit E;
6. Patient's first consent to participate is a Research Study is attached as Exhibit F and the study on Hepatitis C shall be referred to as "HCV";
7. Patient was not properly advised in the consent form, nor did the consent forms comply with federal regulation;
8. Plaintiff, Katherine Muir (A.K.A. Katie Muir) on April 6, 2010 by Dennis McGuire, Regional Counsel, Office of General Counsel, Department of Veteran's Affairs suggested a lawsuit be filed against his client (who is the Defendant, United States of America) attached as Exhibit K;
9. Office of Research oversight (hereinafter designated "ORO") serving primary Veteran's Health Administration (hereinafter designated "VHA") conducted a review of Patient's rights as stated in Exhibit L attached hereto;

JURISDICTION

10. Plaintiff's claim against Defendants under the Federal Tort Claims Act amount others;
11. Patient was a claim for malpractice under the Civil Rights Act of 1871 (42 U.S.C.S. 1983 and others) and related legal fees and costs;
12. Based on concealment of facts, deception, and failure to comply with document requests this action is timely under 28 U.S.C.S. 2401; the agency (V.A.) through its counsel has

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clearly demonstrated it has reopened Patient's proceeding and decision to consider judicial review with the filing within six months;

13. Under pendent jurisdiction all or some of the physicians and mental health providers failed to meet the standard of care involving drug related adverse events (A) the drugs were unsafe for Patient; (B) the drug and/or drugs were prescribed in an unsafe manner; (C) there was a failure to obtain appropriate informed consent;
14. Patient and Plaintiffs have a claim for denial of substantive due process, procedural due process, equal protection under 42 USC §1985;
15. The consent forms used for Patient failed to state the real risk of the experiment referenced in the consent form;
16. Defendants violated the Helsinki Declaration that doctors remain the protector of the life and health of the person on whom clinical research is being carried out;
17. Patient's participation in the study referenced in the release (Exhibit F) was a violation of his rights, privileges, and immunities secured by the First and Fourteenth Amendments of the United States Constitution;
18. The Project officers designated as Defendants active in supervisory capacities incurred supervisory liability by implicating authority approving as knowing acquiesces in the unconstitutional conduct which resulted in the deprivation of Plaintiff's rights;

FACTUAL ALLEGATIONS

19. Plaintiffs reallege Paragraphs 1 through 18 as if fully rewritten herein;
20. Patient during the period of time in question was in a research study involving Interferon and/or Ribeavirin among other drugs;

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21. On or about February 19, 2010 the Administrator for the Estate of David John Muir, Sandra Sykes, filed a claim for damage, injury, or death on the standard form prescribed by the Department of Justice in reference to the United States Department of Veteran's Affairs attached hereto as Exhibit B received on February 25, 2010 as shown on Exhibit C attached hereto;
22. An Amended Claim for Damage, Injury, or Death was filed on the same standard form as stated in the preceding paragraph was signed on June 18, 2010 as shown on Exhibit D attached hereto sent Fed Ex, U.S. Air Bill as shown on Exhibit E attached hereto;
23. Patient was involved in clinical trials involving HCV research at all dates material herein;
24. Patient signed a University of Cincinnati consent to participate in research study attached hereto as Exhibit F consisting of thirteen (13) pages;
25. Patient prior to being enrolled in the research study had approximately over 65% of his body severely burned, was without one hand, and lacked the fingers on his other hand;
26. Patient was suffering from depression and on heavy medications for pain management,
27. The Defendant, Roche Molecular Systems, Inc., had obtained approval to market the product, Amplicor Hepatitis C Virus (HCV) test, see Exhibit G attached hereto being three pages;
28. The device stated in the preceding paragraph was recalled as a Class 1 Recall, being the most serious type of recall and involving situations in which there is a reasonable probability that use of the product will cause serious injury or death, see Exhibit H attached hereto;
29. The principle investigator on the first consent by Patient was the University of Cincinnati Medical Center Institutional Review Board Notification Form being Charles Mendenhall,

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M.D. and co-investigators G. Rosell, M.D., and R. Weesner, M.D. under protocol number 99-06-02, see Exhibit I attached hereto on the second consent by Cincinnati Veteran Affairs was Charles Mendenhall (principle investigator) and Judy Harrer, Ph.D. as a co-investigator;

30. The Patient did not meet treatment of eligibility criteria as shown in Exhibit J attached hereto and the investigators in Paragraph 29 negligently failed to disqualify Patient;
31. Patient's death caused by colonic isihemia should have been detected by endoscopy with colonoscopy as the diagnostic tool, which rudimentary procedure was not performed as misfeasance;
32. Patient did not receive a colonoscopy ;
33. Defendants have failed to provide medical records as requested;
34. Patient for approximately one year prior to his death complained of bloody stool, diarrhea, and episodes and the treatment which was negligently received was an enema;
35. Patient was sent home with drugs to be injected, which was impossible as Patient had no hands and the majority of his body had suffered burns to such a degree that the standard for injection was not possible;
36. Patient received some injections at the VA facility through the stomach;
37. Attached as Exhibit M is the black box warning on the drug Pegasys;
38. Defendant, Jeffrey Goldsmith, did a psychological evaluation of Patient and based on the drugs being taken by Patient under the black box warning for Pegasys as shown in Exhibit M was not eligible even with monitoring and Patient should have been withdrawn from the study;
39. Plaintiffs did not get growth stimulation records, which were requested;

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40. Defendant, Dr. Joseph Morelli, treated Patient without authority and not within the protocol;
41. Patient signed a consent on 12/28/2001 (a copy is attached as Exhibit N);
42. Patient and/or the Plaintiffs have been advised Patient was not eligible;
43. The Defendant, Roche, is the manufacturer of Pegasys knowing that the drug being issued as a study on Patient;
44. Defendant, Schering Corp. is the manufacturer of Interferon and Ribeavirin knowing that these drugs were negligently used in a study on Patient or should have known or should have provided better resource materials;
45. Amgen manufactured Procrit for Centoroc Ortho Biotech Products knowing it was used negligently in a study on Patient or should have known or should have provided better resource materials;
46. Buproprion is distributed by Glaro Smith Kline Research Triangle Park, N.C. 27709 and manufactured by DSM Pharmaceuticals Inc. Greenville, N.C. 27834, which was negligently used on Patient and the distributor should have known or should have provided better resource materials.

WHEREFORE Plaintiffs pray for the relief as follows:

1. That all Defendants release all records under their control, within their storage, or where they otherwise have authority to release in reference to the Patient, David John Muir;
2. That the Defendant drug companies: Roche Molecular Systems, Inc; Glaro Smith Kline Research; Centoroc Ortho Biotech Products, L.P; Schering Corporation;

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Schering Plough Corporation; and Roche Pharmaceuticals jointly and severally have Judgment rendered against them in a sum exceeding $75,000.00;

3. That the doctors conducting the study who failed to comply with the protocol have judgment rendered against them in a sum exceeding $75,000.00;

4. That the doctors who failed to render treatment to the Patient have judgment rendered against them in a sum exceeding $75,000.00;

5. That the doctors who failed to supervise Patient's care as required by state and/or federal rules and regulations have judgment rendered against them in a sum exceeding $75,000.00;

6. That the doctors failing to comply with the black box warnings on the drug literature and ordering the drugs administered to Patient have judgment rendered against them in a sum exceeding $75,000.00;

7. That the Defendants pay the Patient's funeral and interment costs;

8. That the Defendants pay the legal fees and costs incurred herein;

9. That the University of Cincinnati be found liable on the first consent as stated in Exhibit F in excess of $75,000.00;

10. That the Cincinnati Veteran's Affairs Medical Center be found liable on the second consent as stated in Exhibit N in excess of $75,000.00;

Plaintiff, Estate of David John Muir, demands judgment jointly and severally in excess of $5,000,000.00; plus legal fees and costs.

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JURY DEMAND

Plaintiff requests a jury trial as provided by law and the Federal Rules of Civil Procedure.

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